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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/997,023

11/30/2001

R. Sam Niedbala

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NIXON PEABODY, LLP
401 9TH STREET, NW
SUITE 900
WASHINGTON, DC 20004-2128

EXAMINER

ALEXANDER, LYLE

ART UNIT

PAPER NUMBER

1743

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/997,023	Applicant(s) NIEDBALA ET AL.	
	Examiner Lyle A. Alexander	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,7,9,12-23,25,46-52 and 73-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2,4,6-7,9,12-23,25,46-52,73-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' amendments and remarks have overcome the 3/28/07 rejections. Upon updating the search and reviewing file, a new reference will be applied below.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-2,4,6-7,9,12-23,25,46-52,73-76 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shah (USP 4,014,322)[cited by Applicants in the 6/18/03 PTOL-1449].

Shah teach a device(20) for the collection of urine samples comprising a chamber(28), a lid(34) having aperture(38), elongated shaft(40), absorbent/sponge(56) attached to shaft(40) and plate(50) attached to the bottom of the shaft(40) below the absorbent/sponge(56). Absorbent/sponge(56) has a first size prior to sample application where it is the width of slot(52) and a second larger size when the sample is applied that is larger than the distance between slot(52) and slot(54). Sample is expressed from absorbent/sponge(56) by pulling the shaft(40) through the aperture(38) such that the absorbent/sponge(56) is squeezed against the lid(38) and the plate(50).

The claimed "a retaining portion having a retaining portion first end operably connected to a retaining portion second end, the retaining portion first end being coupled to the holding portion second end and the retaining portion second end being movable relative to the holding portion second end, the retaining portion having at least an extended size and a contracted size, the sizes being defined by a distance between

the retaining portion second and the holding portion first end” has been read on the above arrangement of the chamber(28), lid(34) having aperture(38), elongated shaft(40), absorbent/sponge(56) attached to shaft(40) and plate(50) attached to the bottom of the shaft(40) below the absorbent/sponge(56).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shah.

See Shah supra.

Shah is silent to the claimed “ ... perforated disk-like piece formed at a distal end ... “ .

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well-known effects. The choice of making a piece for expressing fluid from a solid piece or a perforated piece would have the well known and predictable results of facilitating the expression of the fluid. Furthermore, it would have been desirable to make a perforated disk to save weight and require less material to construct a perforated disk than a solid disk.

It would have been within the skill of the art to modify Shah and use a perforated disk instead of a solid disk as optimization of a result effective variable and to gain the above advantages.

Response to Arguments

Applicant's arguments with respect to claims 1-2,4,6-7,9,12-23,25,46-52,73-77 have been considered but are moot in view of the new ground(s) of rejection.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Laauwe (USP 4,596,157) and Lennon et al. (USP 4,963,325) teach collecting a biological sample with an absorbent member and subsequently squeezing or expressing the collected sample for further analysis. Both of these references fail to teach or suggest the claimed "... the retaining portion second end being movable relative to the holding portion second end ...". Additionally, with respect to claim 77, these references fail to teach or suggest the claimed retaining portion is an elongate member having a proximal end adjacent the holding portion second end and a perforated disc-like piece formed at a distal end, the perforated disc-like piece comprising the wall, wherein the collector member is made from a fluid absorbing material that is movable along, the elongate member when the collector member has the first collection size".

Wu et al. (USP 7,114,4033) is **not available as prior art**, but teaches a fluid sampling device comprising an absorbent member and a perforated disk that expresses the sample from the absorbent member.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander
Primary Examiner
Art Unit 1743

